



FOOD AND DRUG ADMINISTRATION
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Announcement Number: FDA-9-4019

Opening Date: April 26, 1999

Closing Date: May 28, 1999

Position Title: Interdisciplinary Scientist (401-Biologist, 403-Microbiologist, 1320-Chemist)

Series & Grade: GS-401/403/1320-12/13

Promotion Potential: GS-13

Salary Range: GS-12 - \$48,769 - \$63,436 per annum
GS-13 - \$58,027 - \$75,433 per annum

Area of Consideration: Government Wide
"Preference eligibles or veterans who have separated from the armed forces under honorable conditions after 3 years or more of continuous service may apply."

Type of Appointment: Career/Career Conditional
This position is open to status candidates only.

Relocation expenses: Will not be paid

Organization, Duty Location: DHHS, FDA, Center for Veterinary Medicine, Office of New Animal Drug Evaluation, Division of Manufacturing Technologies, Rockville, Maryland

Condition of Employment: Certain positions within the FDA are subject to strict restrictions on financial holdings (FDA regulated financial holdings). To determine whether this position is affected, applicants are advised to seek additional information during the interview process prior to accepting such a position.

Commissioned Corps candidates may apply.

JOB SUMMARY:

The incumbent serves as a scientific reviewer who evaluates and decides whether the manufacturing chemistry and controls section of applications for animal drugs and medicated feeds should be approved. The incumbent reviews New Animal Drug Applications (NADAs) (original, supplemental and amendments), Investigational New Animal Drugs (INADs), and Master Files (MF's) for technical, chemical, microbiological and pharmacological information. Specific duties include:

- Reviews and evaluates manufacturers data on the manufacture of new animal drugs, prepares written evaluations showing results, determines whether a submission has scientific validity and is adequate to meet the requirements.
- Requests additional data or tests from sponsors and applicants when determined they are needed to establish adequate specifications and/or characteristics of the drug products.
- Determines whether the technical content of labeling are consistent with information submitted in application and comply with the law.
- Recommends field investigations be conducted by FDA District personnel of applicants' facilities to assure compliance with submitted application or petition.
- Reviews protocols for Investigational studies in the area of manufacturing chemistry advising as to their adequacy and recommends modification where needed.
- Prepares a comprehensive summary of the data reviewed and submits substantive recommendations and conclusions.
- Participates in meetings with sponsors to discuss issues pertaining to manufacturing chemistry and controls.
- Performs a variety of related assignments; e.g., serves as member of scientific investigational teams, field investigation teams, ad hoc committees, task forces, and panels and/or project officer for extramural contracts or other Center efforts.

QUALIFICATIONS:

BIOLOGIST, GS-401

Applicants must have either (A) Successful completion of a full four-year course of study in an accredited college or university leading to a bachelor's degree (or higher) with major study in biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position; or (B) A combination of education and experience with courses equivalent to a major, as shown in A above, plus appropriate experience or additional education.

MICROBIOLOGIST, GS-403

Applicants must have either (A) Successful completion of a full 4-year course of study in an accredited college or university leading to a bachelor's (or higher) degree in microbiology, biology, chemistry, or basic medical science which includes at least 20 semester hours in microbiology and other subjects related to the study of microorganisms, and 20 semester hours in the physical and a mathematical sciences combining course work in organic chemistry or biochemistry, physics, and college algebra, or their equivalent; OR (B) A combination of education and experience with courses equivalent to a major in microbiology, biology, chemistry, or basic medical science that included courses as shown in A above, plus appropriate experience or additional education.

CHEMIST, GS-1320

Applicants must have either (A) Successful completion of a full four-year course of study in an accredited college or university leading to a bachelor's (or higher) degree in physical sciences, life sciences or engineering that included 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours of physics; OR (B) A combination of education and experience with course work equivalent to a major as shown in A above, including at least 30 hours in chemistry, supplemented by mathematics through differential and integral calculus, and at least 6 semester hours of physics, plus appropriate experience or additional education.

SPECIALIZED EXPERIENCE is experience which is typically in or directly related to the work of the position.

All applicants must meet the above qualification requirements within 30 days after the closing date of this announcement. In addition, status candidates applying under merit promotion procedures must meet time-in-grade requirements within 30 days after the closing date.

EVALUATION METHOD:

Candidates found basically qualified will be further evaluated by determining the extent to which their work or related experience, education, training, awards, etc., indicate their possession of the knowledge, skills, and abilities (KSA's) described below.

1. Knowledge of scientific principles, theories and practices.
2. Knowledge of laws and regulations relating to drug approval.
3. Ability to communicate findings in writing.
4. Ability to communicate findings orally.
5. Ability to review and evaluate data.

HOW TO APPLY:

- A. Candidates may submit an Application for Federal Employment (SF-171), an Optional Application for Federal Employment (OF 612), resume, curriculum vitae, or any other written format. Your application **must** include the following information:
 1. Title, series, grade, and vacancy announcement number of the vacancy for which you want to be considered.
 2. Full legal name, social security number and mailing address.
 3. Daytime and evening telephone numbers.
 4. For experiences most relevant to this position, include name of employer, dates of employment, job title, start and end dates, and a description of your duties and responsibilities for each job listed.
 5. Average hours worked for each position if other than 40 hours per week.
 6. Name, location and date of educational institutions attended.
 7. Type of degree, if any, and date received.
 8. Major field of study.
 9. List of relevant training including, courses titles, dates, number of hours and name of institution.
 10. Description of honors, awards, and special qualifications, such as language skills or computer skills, along with dates acquired.
 11. Clearly identify U.S. Citizenship (Proof required prior to employment)

B. Additional Information

The following information/documents should be submitted with your application/resume, if checked:

- ☒ 1. Written response to the knowledge, skills and abilities
- ☒ 2. If claiming veterans' preference, DD-214 if claiming 5 points veterans preference
- ☒ 3. Both DD-214 and SF-15 if claiming 10 points veterans preference
- ☒ 4. College transcripts or list of courses, including title, credit hours and grade for each course
- ☒ 5. For status candidates, copy of most recent performance appraisal/evaluation, and a copy of last SF-50, Notification of Personnel Action
- ☒ 6. Applicant Background Survey: Please return the Background Survey with your application. The information you provide is used for statistical purposes. The return of this form will have no impact on your consideration for this position.

Qualifying education gained at colleges and universities in foreign countries must be evaluated in terms of its equivalency to that acquired in American colleges and universities. Applicants educated in whole in foreign countries must submit sufficient evidence, including transcripts, to an accredited private organization for an equivalency evaluation. A letter containing the results MUST accompany the application package. If the highest degree was obtained in the U.S. no further evaluation is necessary.

Veteran's Preference for Federal Jobs:

If you served on active duty in the United States military and received an honorable or general discharged, you may be eligible for veterans' preference. Service starting after October 15, 1976, requires a Campaign Badge or Expeditionary medal, or service connected disability requirements. For information about eligibility requirements, call 912-757-3000 and request Veterans' Preference for Federal Jobs: CE-101

To Claim veterans' preference, attach a copy of your DD-214, Certificate of Release or Discharge from Active Duty, or other proof of eligibility.

- If claiming 5 point veterans' preference, list the dates (month, day, year) and branch of any active duty served.
- If claiming 10 point veterans' preference, attach an SF-15, Application for 10 Point Veteran's Preference, plus the proof required by that form.

*The Defense Authorization Act of November 18, 1997, extended veterans' preference to persons who served on active duty during the Gulf War from August 2, 1990, through January 2, 1992. The law grants preference to persons otherwise eligible and who served on active duty during this period, regardless of where the person served or for how long. The law also authorizes the Secretary of each military department to award the Armed Forces Expeditionary Medal for service in Bosnia during the period November 10, 1995, to a date to be determined. The award of the Medal is qualifying for veterans' preference. More information on veterans' preference is available in the VetGuide that may be found on the U.S. Office of Personnel Management web site at www.opm.gov.

Surplus or Displaced Employees in the Department of Health And Human Services (DHHS) Requesting Special Selection Priority Consideration Under The Career Transition Assistance Program (CTAP)

If you are currently a DHHS employee you may be entitled to special priority selection under the DHHS Career Transition Assistance Program (CTAP). To receive priority consideration, you must:

1. Be a current DHHS employee serving under an appointment in the competitive or excepted service in tenure group I or II, in receipt of (1) a Reduction in Force (RIF) specific separation notice, (2) a notice of proposed removal for declining a directed reassignment or transfer of function outside of the commuting area, (3) a Certificate of Expected Separation (CES), or (4) other official notice that indicates the employee is surplus or eligible for discontinued service retirement (DSR) or as being in a surplus organization or occupation, and the date of the separation has not passed and you are still on the rolls of DHHS. You must submit a copy of the separation notice, CES, or other official notice along with your application in order to receive special priority consideration;
 2. Be applying for a position that is at or below the grade level of the position from which you are being separated. The position must not have a greater promotion potential than the position from which you are being separated;
 3. Have a current (or last) performance rating of record of at least fully successful or equivalent. This must be submitted with your application package;
 4. Be currently employed by DHHS in the same commuting area of the position for which you are requesting priority consideration;
 5. Submit your application (including all required documentation) by the vacancy announcement closing date and meet all the application criteria; and
 6. Be rated well qualified for the position.
- "Well Qualified" means: a surplus/displaced employee must meet the minimum qualifications and eligibility requirements for the position, including any documented selective factor(s), and be rated and ranked under the same procedures as merit promotion applicants to determine the extent to which he/she possesses the knowledge, skills, and abilities (KSAs) to succeed in the position being filled. A cut-off score will be used to determine the well qualified applicant(s).

Displaced Employees Requesting Special Selection Priority Consideration Under The Interagency Career Transition Assistance Program (ICTAP)

If you are a displaced Federal employee you may be entitled to receive priority selection under the ICTAP.

To be eligible for the special selection priority, you must meet all of the following:

- (1) Be a displaced Federal employee;
 - (2) Submit a copy of your current (or your last) performance rating of record of at least fully successful or equivalent;
 - (3) Apply for a vacancy at or below the grade level from which you were or are being separated, that does not have a greater promotion potential than the position from which you have been or are being separated from;
 - (4) Occupy, or was displaced from a position in the same local commuting area of the vacancy;
 - (5) Submit an application (including all required documentation) for a specific vacancy within the time frames established on the announcement and meet all the application and eligibility criteria;
 - (6) Submit proof of eligibility; and
 - (7) Be rated well qualified for the position.
- “ Well Qualified “ means: a displaced employee must meet the minimum qualification and eligibility requirements for the position (including any selective factors), and be rated and ranked to determine the extent to which he/she possesses the knowledge, skill, and abilities (KSAs) to succeed in the position being filled. Under merit promotion procedures, a cut-off score will be used to determine the well qualified applicant(s). Under delegated examining procedures, the displaced employee must receive a score of 90 or better to receive selection priority.

Displaced employees may submit any (one) of the following as proof of eligibility for the special selection priority:

- (1) RIF separation notice, or notice of proposed removal for declining a directed reassignment or transfer of function to another commuting area;
- (2) Documentation, e.g., SF-50, Notification of Personnel Action, showing that you were separated as a result of RIF, or for declining a directed reassignment or transfer of function to another commuting area;
- (3) Official certification from an agency stating that it cannot place an individual whose injury compensation has been or is being terminated;
- (4) Official notification from OPM that your disability annuity has been or is being terminated; or
- (5) Official notification from the Military Department or National Guard Bureau that the employee has retired under 5 U.S.C. 8337(h) or 8456.

Send or bring applications to: Food and Drug Administration
 Office of Human Resources and Management Services
 Attn: Mary Goodson
 Room 211, Metro Park North I, HFA-423
 7520 Standish Place
 Rockville, MD 20855

Faxed copies of this announcement may be obtained by calling (301) 827-4287 or visit our Website at www.Usajobs.opm.gov/a9fda.htm.

Applications received become the property of the Office of Human Resources and Management Services (OHRMS).

Applications submitted in postage paid Government envelopes will not be accepted.

Additional forms and information may be obtained from the address above or by calling Mary Goodson at (301) 827-7332. Candidates must submit a complete application package that is received or postmarked by the closing date of this announcement.

All applicants will receive equal consideration without regard to race, religion, color, national origin, sex, disability, sexual orientation, political affiliation, age (with authorized exceptions) or any other non-merit factor.